

CLAIMS

What is claimed is:

1. A method of applying a drug-polymer coating on a stent,
5 comprising:
dipping a stent framework into a first polymeric solution, wherein
the first polymeric solution comprises a first polymer, a first therapeutic agent,
and a first solvent;
drying the first polymeric solution to form a thin drug-polymer layer
10 on the stent framework;
dipping the stent framework including the thin drug-polymer layer
into a second polymeric solution, wherein the second polymeric solution
comprises a second polymer and a second solvent, and wherein the thin drug-
polymer layer is insoluble in the second polymeric solution;
15 drying the second polymeric solution to form a thin barrier layer on
the first thin drug-polymer layer; and
repeating the steps of dipping the stent framework into the first
polymeric solution, drying the first polymeric solution, dipping the stent framework
into the second polymeric solution, and drying the second polymeric solution until
20 a target drug-polymer coating thickness is disposed on the stent framework.
2. The method of claim 1 wherein the first polymer comprises
poly(ethylene-vinyl acetate).
- 25 3. The method of claim 1 wherein the first polymeric solution
comprises between 0.05 percent and 10.0 percent total solids by weight of the
first polymer.

4. The method of claim 1 wherein the first therapeutic agent comprises camptothecin.

5 5. The method of claim 1 wherein the first therapeutic agent comprises one of rapamycin, a rapamycin derivative, or a rapamycin analog.

6. The method of claim 1 wherein the first solvent comprises a mixture of chloroform and methanol.

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7. The method of claim 6 wherein the first solvent comprises chloroform with a concentration between 80 percent and 90 percent.

8. The method of claim 1 wherein the second polymer comprises one
15 of polyurethane, polycaprolactone, or a blended polymer of polyurethane and polycaprolactone.

9. The method of claim 1 wherein the second solvent comprises tetrahydrofuran.

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10. The method of claim 1 wherein the second polymeric solution comprises a second therapeutic agent.

11. The method of claim 10 wherein the second therapeutic agent
25 comprises camptothecin.

12. The method of claim 1 wherein the first polymer comprises a rigid thermoplastic polyurethane; the first therapeutic agent comprises 5-fluorouracil; the first solvent comprises a blend of tetrahydrofuran and methanol; the second
5 polymer comprises an ester-extended polyurethane; and the second solvent comprises chloroform.

13. The method of claim 12 wherein the second polymeric solution comprises one of an anti-proliferative compound or an anti-inflammatant.
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14. The method of claim 12 wherein the second polymeric solution comprises rapamycin, a rapamycin derivative, or a rapamycin analog.

15. The method of claim 12 wherein the second polymeric solution
15 comprises dexamethasone.

16. The method of claim 1 wherein the first polymer comprises a copolymer of methacrylamide, methacrylate and vinyl alcohol; the first therapeutic agent comprises 5-fluorouracil; the first solvent comprises a mixture
20 of chloroform and water; the second polymer comprises a rigid thermoplastic polyurethane; and the second solvent comprises tetrahydrofuran.

17. The method of claim 16 wherein the second polymeric solution comprises an anti-inflammatant.
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18. The method of claim 16 wherein the second polymeric solution comprises dexamethasone.

19. The method of claim 1 wherein the first polymer comprises a copolymer of methacrylamide, methacrylate and vinyl acetate; the first therapeutic agent comprises dexamethasone; the first solvent comprises ethanol;
5 the second polymer comprises poly(butyl methacrylate); and the second solvent comprises a blend of tetrahydrofuran and methanol.

20. The method of claim 19 wherein the second polymeric solution comprises an anti-proliferative compound.
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21. The method of claim 19 wherein the second polymeric solution comprises 5-fluorouracil.

22. The method of claim 1 wherein the thin barrier layer is insoluble in
15 the first polymeric solution.

23. The method of claim 1 wherein drying the first polymeric solution comprises positioning the dipped stent framework in air after dipping the stent framework into the first polymeric solution, and evaporating the first solvent.
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24. The method of claim 1 wherein drying the second polymeric solution comprises positioning the dipped stent framework in air after dipping the stent framework into the second polymeric solution, and evaporating the second solvent
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25. The method of claim 1 further comprising:
modulating a concentration of the first therapeutic agent in the thin drug-polymer layers to provide a predetermined drug-release profile.

26. A drug-polymer coated stent, comprising:
a stent framework; and
a laminated drug-polymer coating disposed on the stent framework,
5 the laminated drug-polymer coating including a plurality of thin drug-polymer
layers positioned between thin barrier layers, wherein the thin drug-polymer
layers include a first therapeutic agent and a first polymer, and wherein the thin
barrier layers include a second polymer.
- 10 27. The stent of claim 26 wherein the stent framework comprises one
of a metallic base or a polymeric base.
28. The stent of claim 26 wherein the stent framework comprises a
material selected from the group consisting of stainless steel, nitinol, tantalum,
15 MP35N alloy, platinum, titanium, a chromium-based alloy, a suitable
biocompatible alloy, a suitable biocompatible material, a biocompatible polymer,
and a combination thereof.
29. The stent of claim 26 wherein the first polymer comprises
20 poly(ethylene-vinyl acetate).
30. The stent of claim 26 wherein the first therapeutic agent is selected
from the group consisting of camptothecin, rapamycin, a rapamycin derivative,
and a rapamycin analog.
- 25 31. The stent of claim 26 wherein the second polymer comprises one of
polyurethane, polycaprolactone, or a blended polymer of polyurethane and
polycaprolactone.

32. The stent of claim 26, wherein the thin barrier layers include a second therapeutic agent.

5 33. The stent of claim 32, wherein the second therapeutic agent comprises camptothecin.

34. The stent of claim 26 wherein the first polymer comprises a rigid thermoplastic polyurethane; the first therapeutic agent comprises 5-fluorouracil;
10 and the second polymer comprises an ester-extended polyurethane.

35. The stent of claim 34 wherein the thin barrier layers include rapamycin, a rapamycin derivative, or a rapamycin analog.

15 36. The stent of claim 34 wherein the thin barrier layers include dexamethasone.

37. The stent of claim 26 wherein the first polymer comprises a copolymer of methacrylamide, methacrylate and vinyl alcohol; the first
20 therapeutic agent comprises 5-fluorouracil; and the second polymer comprises a rigid thermoplastic polyurethane.

38. The stent of claim 37 wherein the thin barrier layers include dexamethasone.

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39. The stent of claim 26 wherein the first polymer comprises a copolymer of methacrylamide, methacrylate and vinyl acetate; the first therapeutic agent comprises dexamethasone; and the second polymer comprises poly(butyl methacrylate).

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40. The stent of claim 39 wherein the thin barrier layers include 5-fluorouracil.

5 41. The stent of claim 26 wherein a concentration of the first therapeutic agent is modulated to provide a predetermined drug-release profile.

 42. A system for treating a vascular condition, comprising:
 a catheter; and
10 a coated stent coupled to the catheter, the coated stent including a stent framework and a laminated drug-polymer coating disposed on the stent framework, the laminated drug-polymer coating having a plurality of thin drug-polymer layers positioned between a plurality of thin barrier layers, wherein the thin drug-polymer layers include a first therapeutic agent and a first polymer, and
15 wherein the thin barrier layers include a second polymer.

 43. The system of claim 42 wherein the catheter includes a balloon to expand the stent.

20 44. The system of claim 42, wherein the catheter includes a sheath that retracts to allow expansion of the stent.

 45. The system of claim 42 wherein the stent framework comprises one of a metallic base or a polymeric base.

25 46. The system of claim 42 wherein the stent framework comprises a material selected from the group consisting of stainless steel, nitinol, tantalum, MP35N alloy, platinum, titanium, a chromium-based alloy, a suitable biocompatible alloy, a suitable biocompatible material, a biocompatible polymer,
30 and a combination thereof.

47. The system of claim 42 wherein the first polymer comprises poly(ethylene-vinyl acetate).

5 48. The system of claim 42 wherein the first therapeutic agent is selected from the group consisting of camptothecin, rapamycin, a rapamycin derivative, and a rapamycin analog.

10 49. The system of claim 42 wherein the second polymer comprises one of polyurethane, polycaprolactone, or a blended polymer of polyurethane and polycaprolactone.

15 50. The system of claim 42, wherein the thin barrier layers include a second therapeutic agent.

51. The system of claim 42, wherein the second therapeutic agent comprises camptothecin.

20 52. The system of claim 42 wherein the first polymer comprises a rigid thermoplastic polyurethane; the first therapeutic agent comprises 5-fluorouracil; and the second polymer comprises an ester-extended polyurethane.

53. The system of claim 42 wherein the thin barrier layers include rapamycin, a rapamycin derivative, or a rapamycin analog.

25 54. The system of claim 42 wherein the thin barrier layers include dexamethasone.

55. The system of claim 42 wherein the first polymer comprises a copolymer of methacrylamide, methacrylate and vinyl alcohol; the first therapeutic agent comprises 5-fluorouracil; and the second polymer comprises a rigid thermoplastic polyurethane.

56. The system of claim 42 wherein the thin barrier layers include dexamethasone.

57. The system of claim 42 wherein the first polymer comprises a copolymer of methacrylamide, methacrylate and vinyl acetate; the first therapeutic agent comprises dexamethasone; and the second polymer comprises poly(butyl methacrylate).

58. The system of claim 42 wherein the thin barrier layers include 5-fluorouracil.

59. The system of claim 42, wherein a concentration of the first therapeutic agent is modulated to provide a predetermined drug-release profile.

60. A method of treating a vascular condition, comprising:
inserting a drug-polymer coated stent within a vessel of a body, the drug-polymer coated stent including a laminated drug-polymer coating having a plurality of thin drug-polymer layers positioned between a plurality of thin barrier layers, wherein the thin drug-polymer layers include a therapeutic agent and a first polymer, and wherein the thin barrier layers include a second polymer; and
eluting at least one therapeutic agent from the laminated drug-polymer coating into the body.

61. The method of claim 60 wherein the thin barrier layers control an elution rate of each therapeutic agent.

- 5 62. The method of claim 60 further comprising:
 selecting the first polymer and the second polymer based on a predetermined elution rate of each therapeutic agent.